

Atty. Docket No. SEQ-4067-UT
USSN 10/723,670

REMARKS

The Office required restriction between Groups I – XII in the Office action. Applicant elects subject matter of Group I, which includes claims 1-10, 42-45 and 55-57, with traverse. Within Group I, Applicant further elects the sequence of SEQ ID NO: 1 without traverse, and elects polymorphism rs1011058 at position 96535 of SEQ ID NO: 1 with traverse.

Traversal is on the basis that claims 46 and 47 should be included in Group I. Applicant requests that the Office include claims 46 and 47 in Group I as there is no undue search burden: a search for the subject matter of claims 1 and 42 will pertain to the search for subject matter of claims 46 and 47. If required, the Office may request that Applicant elect a species in claims 46 and 47.

Traversal also is on the basis that election of the polymorphism should not be a requirement for restriction, and instead, should be a species election requirement. The Office provides basis for restricting among various SEQ ID NOs, but does not directly provide basis for restricting among individual polymorphisms. Applicant respectfully provides three grounds of reasoning that support a species election requirement instead of a restriction requirement.

1. Office Practice Supports a Finding of a Species Election Requirement

The undersigned representative held an interview with Examiners Stanton and Caputa to determine the relationship of polymorphic species to generic claim 1 herein. The undersigned representative understood from this interview that it was standard Office practice to consider the method of claim 1 and polymorphic variants to which it refers as a classic genus/species relationship. The outcome of this interview supports the application of a species election requirement here.

2. Legal Precedent Supports a Finding of a Species Election Requirement

The Office has required restriction between subject matter within a single claim, claim 1. This practice is impermissible according to controlling legal precedent. *See In re Watkinson*, 14 USPQ.2d 1407 (Fed. Cir. 1990) citing *In re Weber*, 198 USPQ

Atty. Docket No. SEQ-4067-UT
USSN 10/723,670

328, 332 (CCPA 1978) and *In re Haas*, 198 USPQ 334, 336 (CCPA 1978). The courts have definitively ruled the statute authorizing restriction practice (i.e., 35 U.S.C. § 121) provides no authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. In these decisions, the courts expressly ruled there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Office to fashion such a rejection. As noted in *In re Weber* at 334:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim, no matter how broad, which means no matter how many independently patentable inventions may fall within it.

Alleging that a particular claim represents multiple "patentably distinct" inventions is a *de facto* rejection of the patentability of the claim because the claim cannot issue as drafted. In this regard the court noted in *In re Weber, supra*:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not effect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim will never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of fragments would not be described in the specification (emphasis added).

Atty. Docket No. SEQ-4067-UT
USSN 10/723,670

Instead of improperly imposing restriction of a given claim, the Office may limit initial examination to a "reasonable number" of species encompassed by the claim (see 37 C.F.R. § 1.146). This practice strikes an appropriate balance between administrative concerns of the Office and the clear constitutional and statutory rights of the inventor to claim an invention as it is contemplated. See MPEP at § 803.02; *In re Wolfrum*, 179 USPQ 620 (CCPA 1973); and *In re Kuehl*, 177 USPQ 250 (CCPA 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution nor does it force an Applicant to file multiple divisional applications that are incapable of capturing the intended scope of the application. The patent application discloses many polymorphisms in SEQ ID NO: 1 associated with breast cancer. Here, it should be clear that the added cost of filing and prosecuting a great number of patent applications does not strike an appropriate balance between the administrative concerns of the Office and the Applicants' statutory rights as inventors.

Thus, restriction between polymorphic variants is impermissible according to controlling legal precedent, and it is respectfully requested that the Office fully examine the subject matter of the elected claims.

3. Polymorphic Species Do Not Impose an Undue Search Burden

Applicant's specification provides a significant amount of information for polymorphisms in SEQ ID NO: 1 associated with breast cancer. For example, Table 10 on pages 73-74 of the specification provides for each polymorphism the SNP database rs number, chromosome position, position in SEQ ID NO: 1, gene location, and the cancer-associated allele. Thus, Applicant has provided a significant amount of information to facilitate searching, and therefore, no undue search burden is present if a polymorphism is elected in response to a species election requirement.

Atty. Docket No. SEQ-4067-UT
USSN 10/723,670

CONCLUSIONS

Applicants respectfully assert that claims 1-10, 42-47 and 55-57 should be examined based upon a species election of a polymorphism. The Examiner is requested to call the undersigned for any reason that would advance prosecution of the instant patent application.

In the unlikely event the transmittal letter is separated from this document and the Office determines that an extension and/or other relief is required, Applicants petition for any required relief, including extensions of time, and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-3473**.

Respectfully submitted,

Dated: June 19, 2006

By: /Bruce Grant/
Bruce Grant
Registration No. 47,608
BioTechnology Law Group
Customer No. 47,328
Telephone: (858) 623-9470